The influence of different levels of exercise on protein oxidation measured by 13CO2 breath test

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To test whether our breath test differentiates between a baseline state and two different levels of exercise (15 minutes at 30% of VO2 max and 15 minutes at 60% of VO2 max) in 16 healthy volunteers, thereby confirming or denying that protein...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Protein and amino acid metabolism disorders NEC
Study type	Interventional

Summary

ID

NL-OMON45714

Source
ToetsingOnline

Brief title
EPOS

Condition

- Protein and amino acid metabolism disorders NEC

Synonym
protein oxidation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: breath test, protein oxidation, protein status, stable isotopes

Outcome measures

Primary outcome

The total protein oxidation measured during the breath test after two different levels of exercise compared to a rested situation will be used to answer our research question.

Secondary outcome

The urine measurements will be used as secundary research variables. The urea and creatinin will serve as controlling variables on protein intake determined by the food diaries and for the lean mass, respectively.

Study description

Background summary

Disturbed protein metabolism is a major negative determinant for the clinical outcome of patients. The hallmark of disturbed protein metabolism is increased oxidation of amino acids and/or decreased incorporation of amino acids, which leads to loss of muscle mass.

To initiate, guide and evaluate (dietary) intervention, it would be highly useful to be able to monitor the derangements in protein oxidation directly, but until recently a bedside tool to assess protein oxidation was not available.

A recently developed noninvasive low naturally enriched 13C-protein 13CO2 breath test has shown to be able to quantify the oxidation rate of ingested low naturally 13C-enriched milkproteins derived amino acids directly. This breath test seems valuable for patient populations, because it elicits the possibility to develop a simple bedside monitoring tool for quantification of amino acid oxidation and amino acid incorporation. The underlying principle of the test is: 13C-protein + O2 --> 13CO2 + H2O.
A study showed that after 4 weeks of aerobic training in untrained young healthy subjects (average age, y 21 ± 1) had reduced leucine oxidation [1]. A

pilot experiment showed that exercise results in less oxidation of protein compared to a rested situation, which shows that the breath test has discriminative powers and that exercise before protein consumption reduces oxidation of protein.

1. Gaine, P.C., Viesselman, C.T., Pikosky, M.A., Martin, W.F., Armstrong L.E. et al. (2005). Aerobic exercise training decreases leucine oxidation at rest in healthy adults. Human Nutrition and Metabolism, vol. 135, pp. 1088-1092.

Study objective

To test whether our breath test differentiates between a baseline state and two different levels of exercise (15 minutes at 30% of VO2 max and 15 minutes at 60% of VO2 max) in 16 healthy volunteers, thereby confirming or denying that protein oxidation is indeed reduced due to exercise as seen in the pilot experiments.

Study design

Randomized cross-over study.

Intervention

A submaximal Astrandtest to estimate VO2max. 15 minutes cycling at 30% of estimated VO2max and 15 minutes cycling at 60% of estimated VO2max.

Study burden and risks

The subjects will keep a food diary for 3x three days in order to collect data on their habitual diet. On each third day, the subjects will collect 24-hour urine in which urea and creatinine will be measured, which will serve as a measure for muscle mass. Age will be noted. Physical parameters such as height, weight, body mass index, waistcircumference and fatfree mass will be measured and/or determined. Fatfree mass will be measured by bioelectrical impedance, which is a noninvasive method. Body surface area will be calculated upon height and weight, using the formula described by Haycock et al. Taken together, these will serve as their baseline values.

Every subject that wants to participate shall start by filling in the ACSM Risk Classification Form to chart possible heartdisease related problems. Only subjects who score a 'low risk' are allowed to participate in this study. In total there will be three exercisetests performed on a stationary bike. The first is a submaximal Astrandtest to estimate VO2max. The other exercises are in random order: 15 minutes cycling at 30% of estimated VO2max and 15 minutes

of cycling at 60% of estimated VO2max.

The breath tests will be performed under the supervision of the coordinating investigator. The risks of all described items are considered negligible. There is no direct benefit for the subjects. Due to the fact that we will recruit at the Hanzehogeschool, Wiebengacomplex the chances are that the subjects will be enrolled in a healthcurriculum. Therefore it could be very interesting for the subjects to get a sense of what research entails. Especially dieting, fasting and also the breath test. We offer the subjects the possibility to be present at a final meeting which will take place after the results have been analyzed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Male
- Age between 18 - 30 years
- Be able to fast overnight
- Be able to consume a 500 ml test drink within 5 minutes
- Be able to fast for 5.5 hours
- Body mass index between 20 and 25 kg/m2
- Be able to understand the Dutch language
- Score *low risk* on the ACSM Risk Classification form
- Give written informed consent

Exclusion criteria

- Disease and/or being medically treated (e.g. diabetes mellitus)
- Heart condition
- Milk (protein) allergy or intolerance
- Smoking
- Drug use
- Habitual average intake of more than 2 glasses of alcohol per day
- Not able to stop alcohol consumption 2 days before the baseline and the two exercise experiments
- Waist circumference >=102 cm

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-04-2017

Enrollment:	16
Type:	Actual

Ethics review

Approved WMO Date:	17-02-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-12-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22625
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL59615.042.16
OMON	NL-OMON22625